

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors : Magnus Bolmsjö and Sonny Schelin
Serial No. : 10/665,742
Filed : September 17, 2003
Title : Partial-Length Indwelling Prosthetic Catheter using Coiled
Inflation Tube As an Anchor and Methods of Draining Urine
and Flushing Clots
Group Art Unit : 3761
Confirmation No. : 4686
Examiners : Adam M. Marcetich and Leslie Deak

Declaration of Magnus Bolmsjö, Ph.D.

I, Magnus Bolmsjö, Ph.D., declare that the following statements made with respect to the above identified patent application are of my own knowledge and are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above application or any patent issued thereon.

1. I am one inventor of the subject matter claimed in the above patent application.
2. A true and correct copy of my Curriculum Vitae is attached as an exhibit to this Declaration.
3. I have assigned my interest in the invention described in the above patent application to ProstaLund Operations AB, a Swedish company, referred to below as "ProstaLund."
4. Under Swedish law, I have a legal right to receive royalties and/or other compensation for the invention described in the above patent application. However, I have assigned those rights to ProstaLund. Consequently, I am no longer entitled to receive royalties or other compensation with respect to this invention.

5. I was originally a founder and significant shareholder in ProstaLund, but I sold substantially all of my interest in ProstaLund, except for a very small number of shares which probably amount to less than 0.03% of the total shares outstanding of ProstaLund. The ProstaLund stock is not publically traded so there is no certain market for the stock, but I estimate the total value of the stock that I now hold to be less than \$1,000.

6. I am not now an officer or director of ProstaLund. I derive no income or compensation from ProstaLund, except that in connection with this matter I am compensated for my time at the rate of \$200 per hour of time spent in connection with the activities undertaken as described herein, with regard to this patent application and two other related US patent applications of ProstaLund in which I am also a named inventor.

7. I have recently reviewed the above application, which has been published as US patent application 2005/0059929. I previously read and understood the patent application when I signed the filing papers for the application on January 7, 2004. In the following paragraphs 10, 11 and 14 of this Declaration, I refer to the numbered paragraphs of the published US patent application 2005/0059929.

8. I have also reviewed the following parts of the history of prosecution of the above application before the US Patent and Trademark Office: the Office Action of October 29, 2007; the Amendment and Response to First Office Action signed on April 28, 2008; the Office Action of June 5, 2008; the Supplemental Amendment and Interview Summary filed on June 13, 2008; the Office Action of September 19, 2008; and the Amendment in Response to Second Substantive Office Action filed on January 21, 2009.

9. In addition, I have reviewed all of the prior art references applied in the Office Actions specifically identified in the preceding paragraph, and much of the prior art which has been cited but not applied in the Office Actions. I am aware of much of this other prior art as a result of my involvement as an inventor when the above application was filed on September 17, 2003.

10. The above partial-length catheter is a significant improvement over known partial-length catheters, such as those described in and generally represented by US patent 6,494,855 to Rioux, US patent application 2003/0208183 to Whalen and US patent 5,916,195 to Eshel (or its European counterpart 0 935 977), which are referred to below as the "Rioux-, Whalen- and Eshel-type partial-length catheters." The practical difficulties and problems created by prostate gland surgery, as well as practical difficulties, problems and emotional issues resulting from prostate gland surgery and from use of Rioux-, Whalen- and Eshel-type partial-length catheters are described in the published US patent application at paragraphs [0002] to [0008], among others.

11. Because a partial-length catheter extends only through the prostatic urethra and not completely through the entire urethra from the bladder to the exit from the penis, unintended upstream migration can block urine flow and cause painful pressure to build in the bladder, among other things. See published application, paragraph [0009]. An emergency medical procedure is necessary to either remove the catheter from the bladder or to reposition the catheter back to its intended position. The user may have to wait hours before such an emergency procedure can be performed. Medical personnel prefer to avoid the disruption of performing unexpected emergency procedures.

12. Because a partial-length catheter is intended for temporary use of about three weeks following prostate gland surgery, and is not intended as a permanent stent, one of the most important factors involved in the above invention is achieving low costs of manufacturing, using, inserting and removing the partial-length catheter. Low cost facilitates prescription of the device. Simplicity of insertion and removal reduces the time and extent of medical procedures required to insert and remove it. Of course, eliminating or avoiding emergency medical procedures also reduces the cost of use.

13. The use of a coiled section of an inflation tube as a downstream restraint or anchor to resist upstream migration of the partial-length catheter body into the bladder is the basic improvement over Rioux-, Whalen- and Eshel-type partial-length catheters. The coiled section of the inflation tube is an economical downstream

restraint against unintentional upstream migration, and achieves many other significant benefits and advantages that are not available from Rioux-, Whalen- and Eshel-type partial-length catheters.

14. Rioux-, Whalen- and Eshel-type partial-length catheters use a separate downstream restraint, and that downstream restraint must then be attached to the body of the partial-length catheter by a separate mechanical connection. Requiring a separate downstream restraint and attaching that restraint increases the costs of manufacturing Rioux-, Whalen- and Eshel-type partial-length catheters, because of the cost of the additional downstream restraint and the labor-intensive action required to attach it. See published application, paragraphs [0011] and [0012].

15. In contrast, forming a coiled section of the already-existing inflation tube does not require any more cost than a simple, easily-executed, and relatively straightforward technique of thermally reforming a part of the inflation tube into the coiled section. No separate mechanical anchor element is required, and no manufacturing step is required to attach the coiled section to the body of the partial-length catheter. I estimate that the additional costs of the separate downstream restraint and the cost of its attachment in Rioux-, Whalen- and Eshel-type partial-length catheters are likely to add at least 25-35% to the cost of those catheters.

16. All reputable manufacturers of medical products conduct a risk analysis on their products. A risk analysis considers possible ways that the product could fail. Rioux-, Whalen- and Eshel-type partial-length catheters have considerably greater risks of failure, because of the additional parts, the additional manual assembly of those parts, and the more complicated use of those types of products. In contrast, the coiled section of the inflation tube of this invention has fewer risks of failure, because no additional parts are required, no connection of those additional parts is required, and its use requires no significant additional training.

17. The coiled section of the inflation tube contributes to eliminating or reducing the risks of urinary tract infection. Urine has natural infection-fighting characteristics. The coiled section allows the urine to flow over almost the entire

urethra contacted by the coiled section, because the coils contact only a very small area of the urethra. The urine flushes the urethra in the space between the individual coils. In contrast, the solid downstream restraints of Rioux-, Whalen- and Eshel-type partial-length catheters contact and block a significant surface area of the urethra. The large surface contact of Rioux-, Whalen- and Eshel-type partial-length catheters prevents the urine from flushing those areas of the urethra. Germs or bacteria located between the solid contact surfaces and the urethra may continue to build and grow. The evaluation of the above invention with patients showed that there was a very small incidence of urinary infection. The low incidence of urinary infection is believed to result in part from the coiled section of the inflation tube allowing the urine to flush the urethra around the coiled section.

18. The solid downstream restraints of Rioux-, Whalen- and Eshel-type partial-length catheters might become an obstruction to the passage of urine through the urethra, if those solid downstream restraints are moved from their intended positions, for example if the downstream anchor turned sideways. It is not possible for the coiled section of the inflation tube to move in such an unintended manner to block the urine passageway through the urethra. The structure of the coiled section cannot become a blockage.

19. The solid downstream restraints of Rioux-, Whalen- and Eshel-type partial-length catheters are a possible source of irritation to the lining or mucosa of the urethra, which might lead to an unusual sensation or low-level pain experienced by the patient. The inherent flexibility of the coiled section of the inflation tube provides more flexibility to avoid such sources of irritation compared to the rigid downstream restraints of Rioux-, Whalen- and Eshel-type partial-length catheters.

20. Rioux-, Whalen- and Eshel-type partial-length catheters require special equipment and execution of unfamiliar medical practices to insert and remove those devices, which also increases the cost of using those devices. Special insertion tools must accept and hold the separate downstream anchor in position while the partial-length catheter is inserted. The location of the separate downstream anchor in Rioux-,

Whalen- and Eshel-type partial-length catheters makes it impossible to directly connect an insertion tool to the body of the partial-length catheter, because the separate downstream anchor is located between any insertion tool and the body of the partial-length catheter. Medical personnel must learn to use and manipulate those special tools.

21. In contrast to the situation described in paragraph 20, the coiled section of the inflation tube does not interfere with or otherwise prohibit a direct and separable connection with the body of the partial-length catheter with an insertion tool, because the coiled section of the inflation tube extends around the outside of the insertion tool.

22. The typical insertion tool for the above partial-length catheter is a length of flexible tubing. When that tubing is connected to the main body of the partial-length catheter at the separable connection, the assembly may be manipulated in substantially the same manner as a full-length catheter is manipulated. Medical personnel have much prior experience with the insertion and manipulation of full-length catheters, so no special tools, training or other new experience are required to insert the above invention when it is connected to a tubing-type insertion tool. The above invention takes advantage of existing experience of medical personnel to reduce the costs of inserting the device.

23. Eliminating the need to insert a full-length catheter after prostate gland surgery, and then remove it about three days later, and then insert a partial-length catheter, and then remove that partial-length catheter about three weeks later, further reduces medical costs. The separable connection between the tube-type insertion tool and body of the partial-length catheter allows the connected combination to function as a full-length catheter for the first three days or so after prostate surgery until the patient has regained control of the external urinary sphincter muscle. Then, the tube-type insertion tool is disconnected from the body of the partial-length catheter at the separable connection, and the partial-length catheter begins functioning in its advantageous manner as a partial-length catheter. Because the separate downstream restraint in Rioux-, Whalen- and Eshel-type partial-length catheters prevents such a

direct connection, those partial-length catheters cannot assume the functionality of both a full-length catheter and a partial-length catheter, as the present invention can do. Neither can Rioux-, Whalen- and Eshel-type partial-length catheters prevent the need for medical personnel to perform two insertion and removal procedures (one for the full-length catheter and another one for the partial-length catheter), as the present invention can do.

24. Removing the above partial-length catheter is easily achieved by pulling on the inflation tube after the balloon has been deflated. The coiled section of the inflation tube stretches out in length and collapses in a transverse dimension, which reduces the amount of obstruction and contact with the urethra as the partial-length catheter is removed. In contrast, the solid downstream anchors of Rioux-, Whalen- and Eshel-type partial-length catheters are not capable of collapsing, and their full transverse size must be pulled along the full length of the urethra during removal, which may cause irritation or sensitivity to the patient.

25. The removal process may also be complicated in Rioux-, Whalen- and Eshel-type partial-length catheters, under those circumstances where the removal force acts on the main body and not on the downstream restraint object. Without some mechanical aspect or feature for guiding the downstream restraint and the main body of the partial-like catheter simultaneously, that restraint may interfere with or block the removal of the main body of the catheter. In contrast, pulling on the inflation tube to remove the partial-length catheter collapses the coiled section and ensures that it leads and guides the main body of the partial-length catheter as it is removed from the urethra.

26. Another improvement obtained from the coiled section of the inflation tube is a greater ease of restoring the partial-length catheter to its intended position compared to Rioux-, Whalen- and Eshel-type partial-length catheters, if the partial-length catheter should inadvertently migrate toward the bladder. Unexpected upstream migration of Rioux-, Whalen- and Eshel-type partial-length catheters could carry the solid downstream restraint through the orifice of the external urinary sphincter muscle to

a position upstream of the sphincter muscle in the prostatic urethra or prostate gland. To restore the intended position, the orifice through the external urinary sphincter muscle must be expanded. Usually the orifice of the external urinary sphincter muscle may not expand a sufficient amount to permit the solid downstream restraint of Rioux-, Whalen- and Eshel-type partial-length catheters to move downstream through it, so a medical medical intervention may be required in order to restore Rioux-, Whalen- and Eshel-type partial-length catheters to their intended positions under such circumstances. In contrast, pulling on the inflation tube of the present invention will move the coiled section of the inflation tube through the external urinary sphincter muscle, without forcing that external sphincter muscle open. As each coil moves through the orifice in external urinary sphincter muscle, the width of the inflation tube remains constant and is accommodated by the sphincter muscle in the same way that the sphincter muscle constricts around the inflation coil to stop the flow of urine. The width of the inflation tube is all that is required to be accommodated due to the spiral nature of the coil, not the much larger three-dimensional solid downstream restraint of Rioux-, Whalen- and Eshel-type partial-length catheters.

27. If the downstream restraint of Rioux-, Whalen- and Eshel-type partial-length catheters should move into the orifice of the external urinary sphincter muscle, the patient will not be able to control urination by normal constriction and dilation of the external urinary sphincter muscle. The solid downstream restraints of Rioux-, Whalen- and Eshel-type partial-length catheters will hold open the orifice in the sphincter muscle and create an continuously open passageway for urine to drain continuously, under such circumstances. The patient can no longer self-control urination if the solid restraints of Rioux-, Whalen- and Eshel-type partial-length catheters should enter the orifice of the external sphincter muscle. In contrast, if the coiled section of the inflation tube inadvertently moves into the orifice of the external urinary sphincter muscle, the sphincter muscle can still constrict around one of the coils to terminate the flow of urine. This advantageous feature of the above invention eliminates the requirement for

immediate medical procedures to restore the proper position of Rioux-, Whalen- and Eshel-type partial-length catheters before normal urination can be obtained.

28. The coiled section of the inflation tube also makes sizing less critical, because of the reasons set forth in paragraph 27. A slight variation of length may result the coiled section of the inflation tube being located partially or wholly within the orifice of the external urinary sphincter muscle. However under those conditions, the above partial-length catheter still achieves complete functionality, unlike Rioux-, Whalen- and Eshel-type partial-length catheters which require a more precise length to locate the rigid downstream restraint completely downstream of the external urinary sphincter muscle to avoid holding the external urinary sphincter muscle open and preventing the patient from achieving normal urinary control, as is discussed in paragraph 27.

29. Many medical doctors lack the necessary equipment, time and/or commitment to make accurate determinations of length of characteristics of a partial-length catheter, so Rioux-, Whalen- and Eshel-type partial-length catheters are less likely to function correctly, require more attention from medical personnel, and achieve less patient satisfaction, compared to the above partial-length catheter which is less sensitive to dimensions for the reasons described in paragraphs 27 and 28. In addition, requiring less attention by medical personnel also reduces the cost of use.

30. Because of its relationship and similarity to a full-length catheter, due to the coiled section of the inflation tube being separate from the main body of the partial-length catheter and not interacting with the direct connection of a tube-type insertion tool, much of the same equipment used for manufacturing full-length catheters can be used to manufacture the above partial-length catheter. This results in a manufacturing cost savings. In contrast, the separate solid restraints and unusual characteristics of Rioux-, Whalen- and Eshel-type partial-length catheters require special equipment and additional assembly techniques to manufacture and assemble those catheters, thereby increasing cost.

31. I have read US patent 4,531,933 to Norton and US patent 4,813,925 to Anderson, which I will refer to below as the "Norton patent" and the "Anderson patent."

I was not aware of the Norton or Anderson patents at the time that I and Dr. Schelin made the invention described in the above application, but if I had been aware of those patents I do not believe that they would have assisted me, or a person having ordinary skill in this field, in creating the invention described in the above application, even though the Norton patent shows at least one coil or hook at both ends of his stent to act as a retention means and even though the Anderson patent describes a single loop or curl located at each end of his stent to act as a retention means. There are a number of reasons why the Norton and Anderson patents would not have assisted me, or in my opinion another person having ordinary skill in the art of partial-length prostatic catheters, in making the invention claimed in the above application:

a. The retaining coils and loops described in the Norton and Anderson patents are located at opposite ends of urine drainage structures of both stents. It would have been impossible to include a coiled or looped section at both ends of the urine draining structure in our invention, because the urine draining structure must stop upstream of the external urinary sphincter muscle to allow the external urinary sphincter muscle to control urination. Permitting the external urinary sphincter muscle to control urination is an important aspect of the above described catheter, as described. Including a retention coil, loop or curl on the opposite ends of the urine drainage structure would require the urine drainage structure to extend through the external urinary sphincter muscle to restrain against upstream movement from a position located downstream of that sphincter muscle. Under those circumstances there would have been no control over urination by the external urinary sphincter muscle because the urine drainage structure would extend through it.

b. Neither the Norton patent nor the Anderson patent explains how an anchoring mechanism at opposite ends of the stent can be disassociated from the urine drainage structure to allow an external urinary sphincter muscle to control urine drainage.

c. The stents of the Norton and Anderson patents are intended to be inserted into the ureter which extends between the renal pelvis (kidney) and the

bladder. I am not aware that the ureter which extends between the kidney and the bladder has any muscle which voluntarily controls urine flow. It is my understanding that there is a repeating involuntary peristaltic movement of the muscles which surround the ureter to gently push the urine from the kidney to the bladder. The physiology of the kidney-bladder urine drainage function does not involve controlling urine by voluntarily opening a sphincter muscle to release a relatively high volume flow of pressurized urine expelled by the bladder through the urethra to the external opening in the penis.

d. I do not believe that a repeating involuntary peristaltic muscle movement in the ureter is similar to the occasional voluntary controlled release of pressurized urine by the external external urinary sphincter muscle. As far as I am aware, the urethra from the bladder to the exterior opening in the penis is passive during urine flow, and no pressure is applied by the urethra. The flow of urine occurs as a result of significant pressure applied by the muscle surrounding the bladder.

e. The significant pressure applied to the urine by the bladder causes the urethra to expand when the pressurized urine flows through it. Once the external urinary sphincter muscle opens, the part of the urethra downstream of the external urinary sphincter muscle also expands because of the pressure from the urine flowing through the urethra. The expansion downstream of the external urinary sphincter muscle means that the downstream restraint or anchor located at that position must still function, even though there is some change in size of the urethra due to the pressurized urine. It is not apparent to me that the low pressure peristaltic action of the ureter is sufficiently similar to the pressurized expansion of the urethra downstream of the external urinary sphincter muscle during urination, which leads to the question whether the coils, loops and curls discussed in the Norton and Anderson patents would function in the environment of the urinary canal downstream of the external urinary sphincter muscle. The Norton and Anderson patents do not answer this question.

f. The question raised in the preceding subparagraph e is further complicated by the disclosure in both the Norton and Anderson patents of a relatively large coil, loop or curl which does not contact a canal. The end coils, loops and curls

shown in the Norton and Anderson patents extend into an open volume of the kidney and the bladder, and that open volume is not comparable to the in the urethra downstream of the external urinary sphincter muscle where the restraint must be effective. It appears that the end coils, loops and curls shown in the Norton and Anderson patents depend on a relatively large size to achieve the restraint function, and that restraint function is accomplished by the relatively large difference in size of the size of the coils, loops and curls contacting the smaller opening in the bladder and the kidney at the ureter. A large size contact structure would not be possible to use in the more limited space of the urethra downstream of the external urinary sphincter muscle, because the urethra is about the same size along its length, even though it expands slightly when conducting pressurized urine. The Norton and Anderson patents do not answer questions about the size of the coils, loops or curls when used in a more confined passage similar to the urethra.

g. The Norton patent describes that the excess amount of the multi-turn coil in the bladder can be clipped and removed so long as one coil is left in the bladder. The fact that a single coil left in the bladder is stated to be sufficient to prevent migration indicates to me that it is the relatively large size of the single coil which interacts with the opening between the ureter and the bladder that prevents migration, and that the size of the restraint is the most important factor. Nothing in the Norton and Anderson patents describes functionality in a more confined space, as is required by the coiled section of the inflation tube operating as a restraint in the described in the above patent application.

h. The Anderson patent describes the loops and curls formed in a plane parallel to the axis of the center of coil which holds the ureter open. Fig. 6 of the Norton patent shows a similar "J hook" configuration at one end of the stent. The orientation of the loops, curls and J hook configuration in a plane parallel to the axis of the main coil supports the idea that it is the size of the loop, curl or J hook configuration which achieves the restraint, as opposed to the effectiveness of the restraint in the confined surface of the urethra downstream of the external urinary sphincter muscle.

i. A loop, curl or J hook configuration would create a serious problem for insertion and removal of the partial-length catheter, because the loop, curl and J hook configuration would be oriented perpendicularly to a direction which would facilitate cooperation with an insertion tool as described in the above patent application. The stents described in the Norton and Anderson patents are inserted with a center wire that straightens them out so that they assume a linear configuration. Once at or near the desired location, the center wire is removed so that the devices change into the coiled, loops, curled and J hooked shapes. Inserting a wire in the inflation tube in the catheter described in the above application is not advisable, because that wire might inadvertently create an opening which would prevent inflation, or possibly even enter the balloon and puncture the balloon.

j. Neither the Norton nor the Anderson patents describe an inflation tube. There is no need for such an inflation tube in either stent because a coil, loop or curl is used at the upstream end to resist downstream movement. The coil, loop or curl does not require inflation or any other external energy source to function as a restraint. In the invention described in the above application, a balloon is used as the upstream restraint to resist against downstream movement. The balloon is very important, because a substantial restraint structure is required to resist the pressure from the bladder during urination, to prevent the pressurized flow of urine from pushing the partial-length prostatic catheter downstream through the external urinary sphincter muscle. The inflation tube is needed to inflate the balloon after the partial-length catheter has been inserted, and to periodically re-inflate the balloon if it should lose pressure. Because the Norton and Anderson patents have no inflation tube or any structure similar to an inflation tube, they do not suggest to me any applicability or relationship to the type of partial-length catheter that requires an inflation tube and a balloon.

k. As discussed above, Norton and Anderson explain the need for a retaining coil or loop on both ends of the urine draining structure. Nothing in the Norton or Anderson patents suggests that a retaining coil can be used on any part of their stents other than on the urine draining structure, because there is no other part of those

stents. The Anderson patent shows an infusion tube 36 for delivering fluid into the kidney, but the loop 14 is not formed in that infusion tube 36. The infusion tube may be detached from the stent at a coupling 37. Forming the loop in the removable infusion tube 36 would eliminate the downstream loop when the infusion tube was detached.

l. Another factor involved in the invention described in the above application is using the inflation tube as a way to conveniently remove the partial-length prostatic catheter after the need for its use ends. Pulling on the inflation tube, after releasing the air pressure and collapsing the balloon, allows removal of the catheter described in the above application without the need to execute a significant medical extraction procedure. The Norton patent does not describe removal. The Anderson patent does not describe the coupling 37 as being sufficiently strong to permit the infusion tube 36 to pull the stent from the ureter. Of course, once the infusion tube of the Anderson patent is removed from the stent, it can no longer be used for removal. Removing the stent from the kidney-bladder ureter may be an entirely different matter than removing the stent through the urethra from the bladder to the exterior opening in the penis. It appears to me that both the Norton and the Anderson patents requires a significant medical extraction procedure of the type which the catheter described in the above application avoids by pulling on the inflation tube.


m. The upper end of the stent described in the Anderson patent is open to conduct urine or to conduct an irrigating fluid into the kidney. Both ends of the stent described in the Norton patent are open to conduct urine. The inflation tube in the catheter described in the above application must remain closed to the flow of urine or any other biological liquid present in the human urinary system, because otherwise the balloon will deflate. The inflation tube of the catheter of the above application is unrelated in purpose or function to the infusion tube of the Anderson patent.

32. For at least the reasons described in paragraph 31 above, even when the Norton and Anderson patents are considered with the Rioux-, Whalen- and Eshel-type partial-length catheters, this combination of subject matter does not lead me, or in my opinion a person having ordinary skill in this field, to a partial-length prostatic catheter of

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the type claimed in the above application in which a coiled section of the inflation tube acts as an anchor or were straight in the urethra downstream of the external urinary sphincter muscle to resist upstream movement, without requiring extra parts to be added and without significantly increasing the cost to construct of the partial-length catheter of the type which has an inflation tube that connects to a balloon that acts as an upstream restraint against downstream movement.

The above statements conclude this Declaration.



Magnus Bolmsjö, Ph.D.
February 20, 2009

Curriculum Vitae of Magnus Bolmsjö, PH.D.

Personal Information

Born: 1950

Status: Married, 3 children.

Address: Clemenstorget 4, 222 21 Lund, Sweden

Citizen and Resident of Sweden

Fluent in English and Swedish.

Academic and Professional Achievements

Ph.D. degree from the Department of Radiation Physics, Lund University, 1981.
Thesis: "The physical and physiological aspects of xenon isotopes in nuclear medical applications". The thesis was about the use of radioactive xenon isotopes for measuring physiological variables, e.g. the brain blood flow.

Associate Professor of Physics, 1985, Lund University.

I have been the tutor or advisor for the following two clinical Ph.D. theses at the Universities in Uppsala and Lund, respectively:

- Wagrell L, Feedback thermotherapy for benign prostatic enlargement - a clinical and methodological evaluation, Ph.D thesis, Uppsala University, Uppsala Sweden 1999; ISBN 91-506-1383-9.
- Schelin S, Development of Feedback Microwave Thermotherapy in Symptomatic Benign Prostatic Hyperplasia, Ph.D thesis, Lund University, Lund Sweden 2006; ISBN 91-628-6717-2.

I have been invited as an opponent or a principal examiner of Ph.D. candidates in Universities in Denmark on two occasions.

My base education is in mathematics and physics with emphasis on medically oriented physics. I am also well acquainted in electronics, computer science and medicine and communicate easily with medical professionals.

In 1990, I founded ProstaLund AB – a Swedish Med-tech firm that makes devices for treatment of prostatic diseases. I was the executive VP for research & development between 1990 and 2003. From 2003-2006, I was the company's president and chief executive officer. I implemented ISO 9000 and QSR in the

company and managed the approval process for Premarket Approval (PMA) in the US for the company's product line, including numerous visits to the FDA and on site inspections. ProstaLund's technique and equipment for non-surgical treatment of BPH is one of a few approved for use in the United States.

After 15 years with ProstaLund, I decided to leave the company during the summer 2006 to take on new projects within the field of quality assurance and validation.

Summary of Scientific Activities

In parallel with my Ph.D. work, I was also engaged in the development of the first MRI system in Sweden and a hyperthermia system for treatment of superficial and deep-sited tumors.

During the 1980's I was a researcher at the Lund University, Department of Radiation Physics, and worked together with Prof. Bertil Persson, Prof. Lars Olof Hafström and others on various projects including MRI, nuclear medicine and hyperthermia.

Over the last ten years I have conducted research in collaboration with surgery and urology clinics in Sweden, US, Germany and Chile as head of the research department at ProstaLund. The main objective of that research was to establish a scientific base for heat treatment – how it works and what the biological rationale for it is – and to develop, optimize and document microwave minimal invasive treatment for prostate enlargement (BPH). I led the research activities at ProstaLund, set up and arranged collaboration with laboratories and clinics throughout the world, managed FDA-controlled randomized clinical studies, established that ProstaLund's BPH treatment was thoroughly documented with published articles in international peer-reviewed magazines, and obtained approval by the FDA and CE-mark in Europe for ProstaLund's BPH treatment. Over the years, more than 30 peer-reviewed scientific articles have been published in international high-rated journals about the ProstaLund BPH treatment by various research and clinical groups, both on the technology and the biological rationale for it, including an important study on the heat sensitivity of human prostate cells, as well as clinical studies comparing the ProstaLund method with surgery. Numerous posters and other presentations have been presented at large international meetings.

Summary of Business Activities

Below is a short summary of activities I have been involved with in conjunction with management responsibilities at ProstaLund, in addition to common business managerial and operating duties on a day-to-day basis.

- Implementing a quality system in full compliance with FDA and European requirements.
- Obtaining FDA Pre-Market Approval (PMA).
- Patent litigation in the US. ProstaLund was sued by a competitor 2001 but counter fought vigorously and eventually won the case.
- Medical malpractice lawsuit in the US which eventually settled on favorable terms.
- Establishing sales channels throughout Europe.
- Setting up a sales office and organization in the US, including recruiting sales people, nurses and managing director.
- Negotiating contracts and agreements.
- Raising venture capital (VC) funding
- Managing validation of a computerized business system for a pharmaceutical company according to the GAMP4 and GAMP 5 guidelines.

Because the Med-tech industry is heavily regulated by the FDA and European regulatory bodies, I have conducted research that is in agreement with current Med-tech regulatory quality standards such as the FDA's QSR system and the European ISO 13485:2003 which emphasizes good operating standards on documentation, verification and validation.

The Swedish Research Council – a Swedish governmental agency -has recently engaged me as an external expert to review applications for funding within the Med-tech field.

Inventions

I am the named inventor or coinventor of the following 18 granted US patents and published US patent applications, including the above application, most of which relate to urological treatment and techniques for facilitating urine drainage:

1. US Patent No. 5,964,791 - "Apparatus for Heat Treatment of Tissue"
2. US Patent No. Re 38,299 (Reissue of 5,964,791) - "Apparatus for Heat Treatment of Tissue"
3. US Patent No. 6,119,045 - "Device for Maintaining a Passage for Urine through the Prostate"
4. US Patent No. 6,355,015 - "Medical Device for Internal Heat Treatment and Drug Delivery"
5. US Patent No. 6,366,818 - "Method and Device for Combined Heat Treatment of Body Tissue"

6. US Patent No. Re 40,472 (Reissue of 6,366,818) - "Method and Device for Combined Heat Treatment of Body Tissue"
7. US Patent No. 6,445,957 - "Method and Device for Supply for Heat"
8. US Patent No. 6,524,270 - "Method and Device for the Treatment of Prostate Tissue"
9. US Patent No. 6,584,361 - "Method and Device for Heat Treatment of Body Tissue"
10. US Patent No. 6,596,017 - "Device for Heat Treatment of Body Tissue"
11. US Patent No. 6,626,876 - "Method and Apparatus for Self-Draining of Urine"
12. US Patent No. 6,852,105 - "Method and Apparatus for Insertion of Self-Draining Urine Apparatus into Bladder"
13. US Patent No. 6,868,290 - "Thermotherapy Catheter and Method of Prostate Thermotherapy with Improved Guide and Heat Confinement"
14. US Patent No. 7,041,090 - "Method and Apparatus for Self-Draining of Urine"
15. US Design Patent D468,420 - "Cabinet for Medical Articles"
16. US Patent Application 2005/0059929- "Partial Length, Indwelling Prosthetic Catheter Using Coiled Inflation Tube As an Anchor and Methods of Draining Urine and Flushing Clots"
17. US Patent Application 2005/20080399- "Urinary Catheter and Method with Increased Resistance to Obstructions"
18. US Patent Application 2006/0111691- "Partial Length Indwelling Urinary Catheter and Method Permitting Selective Urine Discharge"

Patents and patent applications corresponding to these US patents and patent applications have been granted and filed in many countries outside of the United States.

20 Selected Publications

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